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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,943	01/25/2001	Eyal Raz	UCSD-173CON	8209

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
02/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/770,943	RAZ ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11-26-08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-36,38-40 and 42-45* is/are pending in the application.

4a) Of the above claim(s) *40 and 42-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-26-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 11-26-08 has been entered into the record. Claims 1-31, 37 and 41 have been cancelled. Claims 32-36, 38-40 and 42-45 are pending. Claims 32-36, 38 and 39 are under examination. Claims 40, 42-45 are withdrawn as drawn to non-elected nucleic acid species and non-elected peptide species.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 40 and 42-45 drawn to a species of invention nonelected with traverse in the responses filed 12-8-03 and 12-4-06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

The amendment to correct claim 32 is noted.

The rejection of claim 41 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of the claim.

The rejection of claim 36 under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (WO 91/16901, published November 14, 1991) in view of Barsoum et al (WO 94/04686, published March 3, 1994) is withdrawn in view of the amendment to the claims.

Rejections Maintained

Claims 32-35, amended claim 36, 38 and 39 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for all previous reasons made of record and reasons herein.

The claims are drawn to a *pharmaceutical composition* comprising *a nucleic acid of a particular structure conjugated to an autoantigen* wherein the nucleic acid inhibits production of one or more recited cytokines. Claim 36 has been amended to include "targeting peptide" that broadly encompasses autoantigen, because an autoantigen would necessarily target the nucleic acid to autoreactive B and T cells.

Applicants argue that the office has not provided convincing rationale. This is not persuasive on its face as the rejection of record and rebuttal is replete with evidence and argument. Applicants again point to the specification. Applicants point to areas of the specification that are not on point to the claimed invention as set forth above. Applicants argue that the ISS can be conjugated. This is not issue. The issue is the autoantigen-ISS conjugate as it relates to a the "pharmaceutical composition" that is described in the specification for the treatment of autoimmune disease as set forth in the specification. The argued examples are not inhibition of autoimmune directed cells, the claimed invention is not demonstrated to be efficacious either in vitro or in vivo, or in any in vitro model that is predictive of in vivo efficacy. Applicants are clearly not pointing to evidence in the specification for enablement of the instantly claimed invention. Applicants argue that one skilled in the art would reasonably expect that an ISS conjugate would be at least as efective as the conjugate. This is not persuasive, the skill in the art at the time of invention in 1997 clearly thought that immune deviation was unpredictable, could exacerbate autoimmune disease and that administration of autoantigen would exacerbate autoimmune disease. Applicants again argue Cho et al to provide evidence that co-administration of antigen-ISS provided for a more potent Th1 response than antigen as compared to ISS alone or in combination with antigen. This is not persuasive because; developments after the filing date the specification must have been enabling at the time

the invention was made and developments after the time of filing are of no consequence to what one skilled in the art would have believed at the time of filing (*In re Wright*, 27 USPQ2d 1510). Further, the issue with the state of the art at the time of the invention that immune deviation as being unpredictable of therapeutic results in autoimmune disease was clearly set in the previous office actions. Applicants have not established that the Th2 response provides for therapy of autoimmune disease as is requisite of the claimed pharmaceutical composition. The issue with respect to the Th2 response, autoantigens and ongoing autoimmune disease treatment is not as simple as generating a Th2 deviated response. The complexities of autoimmune disease, the issue of administration of autoantigen and immune deviation are many. The unpredictability and complexity of the in vivo milieu is well established in the art and articulated by the references provided by the Office. It is noted that Applicants provide a plethora of references at pages 14-17 that allegedly demonstrate efficacy. This is not persuasive because it does not speak to the state of the art at the time the invention was made (1997) and does not utilize any specie within the claimed genus. Applicants address each of the individual references provided by the office and indicate that each of them does not speak to the instantly claimed conjugate. This is not persuasive because it is the body of evidence that indicates that in 1997 the claimed conjugates would not have been enabled for therapy of autoimmune disease and one skilled in the art would have reason to doubt the assertion of the specification to the contrary. It remains that the conjugate has not been tested or evaluated in any in vitro assay that is reasonably predictive of in vivo therapeutic success. Applicants argue that post filing evidence is acceptable where the art describes successful carrying out of a method or use of a composition. It is noted none of the post filing references cited by Applicants use the instantly claimed pharmaceutical composition (ISS-autoantigen conjugate) for therapeutic efficacy of autoimmune disease and individually do not demonstrate the state of the art at the time the invention was made.

The rejection is maintained for reasons made of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner